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GB 1537679

GB 1450201

GB 1417962

GB 1163452

GB 1142323

GB 0801170

GB 0778813

GB 0439085

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(54) Wound dressings for burns

(57) Low adherency wound dressings consist of a wound facing layer and an absorbent layer, the wound facing layer comprising a conformable apertured film and the absorbent layer comprising a conformable hydrophilic foam; materials therefor and processes of manufacture thereof are described.

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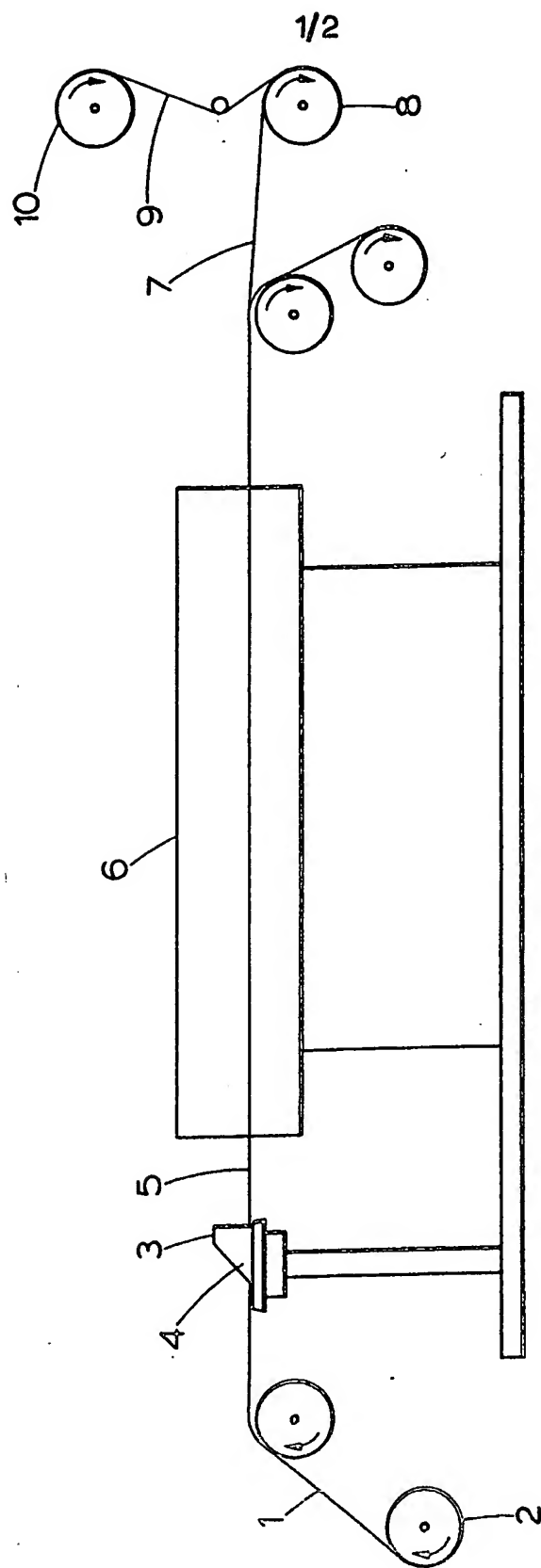
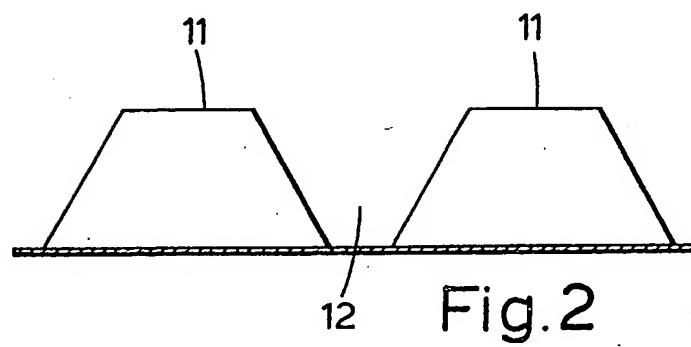
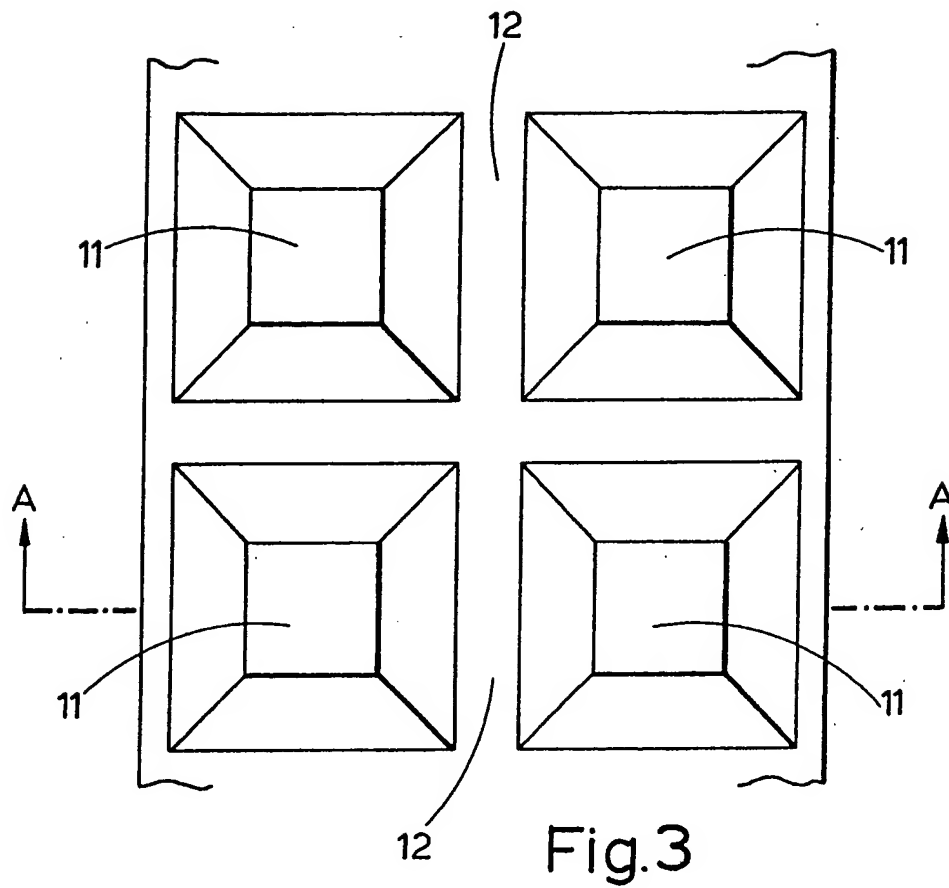


Fig.1



SPECIFICATION

Wound dressing, manufacture and use

- 5 The present invention relates to an absorptive wound dressing suitable for use on burns or other wounds which dressing has a reduced tendency to adhere to the wound. The present invention also relates to the manufacture and
- 10 use of such dressings.
- Burns and other related wounds such as donor sites and the like present a serious problem in that they tend to produce large amounts of exudate which can cause conventional dressings to become saturated or to stick to the wound or even to become infected. One method of covering such wounds has been to cover the wound with a material into which new epithelial or fibroblast growth
- 15 can penetrate. Dressings of this kind are disclosed in U.S. Patents Nos. 3526224, 3648692 and 3949742.
- However such dressings can be extremely painful to remove and often require surgical
- 25 excision. A fundamentally different approach requiring a fundamentally different type of dressing is to employ materials that are designed to reduce the propensity to adhere to the wound. Dressings of this kind are disclosed in British Patent No. 439085, French Patent No. 947609, United States Patents Nos. 3543750, 2923298 and British Patent No. 778813 which later patents cover successfully used materials such as Melolin ("Melolin" is a registered Trade Mark of T.J. Smith and Nephew Limited, Welwyn Garden City, Herts., U.K.). One more recent attempt at non-adherent dressings is United States Patent No. 3709221 which discloses a dressing
- 40 having an outer microporous, liquid repellent fibrous layer, an inner macroporous fibrous layer and an absorbent intermediate layer which was also envisaged as normally being fibrous. In order to reduce the tendency of
- 45 this material to adhere to the wound the inner layer had to be treated with an agent to render it non-wetted by body liquid. It is now realised that it would be desirable to provide a dressing in which the wound facing layer did not require special treatment. As it will become apparent hereinafter it has now been discovered that by avoiding fibrous materials it is possible to produce a dressing with reduced tendency to adhere to wounds without the need for special treatments. An attempt at producing an absorbent dressing is described in U.S. Patent No. 3888748 which describes a dressing fabricated from at least four sheet materials. The wound facing part of
- 60 the dressing apparently consists of a grid or scrim coated with polyethylene in such a manner that the polyethylene surrounds the filaments of the grid and collects any loose thread or particle that may be present in the
- 65 core material. It is now realised that it is

desirable to avoid the use of wound facing layers that can allow such penetration of the central layer to the wound surface. It has also been realised that it would be desirable to

- 70 provide a material that was highly conformable to the wound so that it is possible to minimise the quantity of exudate between the wound surface and the dressing. U.S. Patents Nos. 3709221 and 3888248 disclose materials which are bonded along their edges which may reflect a desire to improve conformability. The dressing of the present invention allows for bonding over the whole of the operative area while retaining flexibility.
- 80 Accordingly the present invention provides a low adherency wound dressing which consists essentially of a wound facing layer and an absorbent layer characterised in that the wound facing layer comprises a conformable
- 85 apertured film and the absorbent layer comprises a conformable hydrophilic foam.
- Normally the two layers of the dressing of this invention are attached in a contiguous and co-extensive manner; that is the dressing
- 90 is normally provided in the form of a laminate.
- The conformable apertured film of the dressing of this invention acts as a low adherency wound facing layer. This layer allows wound exudate to pass to the absorbent layer
- 95 but prevents the absorbent layer making direct contact with the wound surface.
- Preferably the apertured film is sufficiently conformable to allow the wound dressing to conform to the body contours and thereby
- 100 maintain overall contact with the wound surface to ensure that exudate from the wound is absorbed.
- It is also desirable that the apertured film should be sufficiently elastically extensible to
- 105 adjust to any dimensional changes in the absorbent layer which may occur, for example, expansion on liquid uptake.
- Normally the apertured film is made of a pharmaceutically acceptable water insoluble
- 110 polymer. Preferred polymers for use are elastomers. Suitable elastomers include polyurethanes, polybutadiene and the like.
- The preferred material for the apertured films are thermoplastic polyurethanes.
- 115 Preferred thermoplastic polyurethanes are linear polyurethanes containing polyether or polyester groups. Suitable linear polyester polyurethanes are disclosed in U.S. Patent Specification No. 2,871,218. Suitable linear polyether polyurethanes are disclosed in U.S. Patent Specification No. 2,899,411. Favoured thermoplastic polyurethanes include Estanes from B.F. Goodrich Corp. Preferred solution casting grades are Estane 5714F1, 5702 and
- 120 5703. A preferred extrusion grade is Estane 580201.
- Suitable polybutadienes are 1,2 polybutadienes. Favoured 1,2 polybutadienes contain a major amount of syndiotactic 1,2 polybutadiene, have a crystallinity of 25% to 30% and
- 130

an average molecular weight in excess of 100,000. Preferred 1,2 polybutadienes are known as RB 810, RB 820 and RB 830 made by Japan Synthetic Rubber Company.

- 5 Non-elastomers such as polyolefins, polyamides and the like are less favoured but can be used where elastic properties are not required in the wound facing layer.

- The number and size of the apertures in the
10 apertured film will be sufficient to allow the wound exudate to pass through the film to the absorbent layer. Most aptly the apertured film is adapted so that the size of apertures in combination with the thickness of the film
15 prevent the absorbent layer contacting the wound surface. Suitable apertured films have apertures with a dimension of from 0.05 to 4mm, more aptly from 0.05 to 2.5mm or 0.05 to 2.0mm and preferably from 0.1 to
20 2.5mm. Suitable apertured films have a thickness of 0.01 to 2.5mm, typically of 0.01 to 0.25mm and preferably of 0.05 to 0.5mm. Favoured apertured films of the invention have 4 to 40 apertures per cm with a dimension of 0.05 to 2.5mm. The wound face of
25 the apertured film suitably will have 15 to 80% of its area void (the apertures), more suitably will have 25 to 75% of its area void and most suitably will have 35 to 65% of its
30 area void.

The conformable apertured film can be in any convenient form such as a perforated film or net.

- In a favoured aspect of the invention the
35 apertured film is in the form of a net which is preferably an integral net. The term 'integral net' means a net in which the strands and junctures are formed integrally during manufacture.

- 40 The integral net of the wound dressing of the invention can have any convenient form depending on the chosen arrangement of strand, juncture and hole areas and also their shapes and relative size.

- 45 In one preferred form the net consists essentially of longitudinal and transverse strands intersecting at right angles to give a square grid hole pattern.

- Suitable nets of this type aptly have 2 to 40
50 strands per cm, desirably 4 to 40 strands per cm and preferably 2 to 24 strands per cm in both longitudinal and transverse directions.

- Variations on the square grid pattern can give other desirable forms of the integral net.

- 55 Unequal density of strands in either the longitudinal or transverse directions will give rectangular hole areas. Continuous parallel strands in one direction with a staggered arrangement of connecting strands in the
60 other direction will give a "brickwork" pattern. Other apt forms of the integral polymer nets can have strands at an angle to the longitudinal or transverse direction (that is diagonal strands). Another preferred form of
65 the integral polymer net can have a staggered

arrangement of circular or approximately circular (for example hexagonal) arrangements of strands and hole areas. The integral polymer net can be in the form of a mixed pattern of two or more of the arrangements if desired.

- 70 The apertured film used in this invention aptly will have a weight of 10gsm to 80gsm and preferably will have a weight of 15gsm to 50gsm.

- 75 In another aspect the invention provides a low adherency wound dressing which consists essentially of a wound facing layer and an absorbent layer characterised in that the wound facing layer comprises a conformable
80 integral net of elastomer and the absorbent layer comprises a conformable hydrophilic polymer foam.

- The desirable conformability of the wound dressing of the invention is consistent with the
85 use of elastomeric materials such as integral nets of polyurethane or other elastomer.

- Suitable integral nets of polyurethane or other elastomer will have an elongation at break of 100% to 800%, desirably of 200%
90 to 750% and preferably of 300% to 700% when measured as a 2.5cm wide strip at 30 cm/min strain rate at 20°C.

- Other suitable conformable apertured films are thin flexible polymer films which have
95 been perforated. Suitable perforated films are disclosed in British Patent Specification Nos. 1,398,011 and 851,473. Yet other suitable conformable apertured films are integral nets of polyolefines such as those disclosed in
100 British Patent Specification Nos. 914,498 and 1055963.

- The conformable hydrophilic polymer foam absorbent layer used in the dressing of this invention is adapted to be capable of absorbing the wound exudate e.g. from a burn. It is desirable that the hydrophilic foam layer absorbs the wound exudate rapidly as this enhances the low adherency properties of the dressing. Such rapid absorption prevents pooling
105 of exudate between the dressing and the wound and it has been found that this prevention of pooling is desirable.

- Suitable conformable hydrophilic foams will normally be flexible, open cell foams. The
115 ability of open cell foam to absorb and retain fluids depends to some extent on the size of foam cells and the porosity of the foam.

- Suitable open cell hydrophilic foams of dressings of the invention have a cell size of 30
120 microns to 700 microns and preferably a cell size of 50 microns to 500 microns. Apt open cell hydrophilic foams of dressings of the invention have 20% to 70% and preferably 30% to 60% of the total membrane area of
125 the cells as membrane openings. Such open cell foams permit transport of fluid and cellular debris into and within the foam.

- Apt foams may be polyurethane, carboxylated butadiene styrene rubber, polyacrylate or
130 other like foam. Such foams may be made of

hydrophilic materials per se or may be treated to render them hydrophilic, for example with surfactants. It is much preferred to use foams which are made of polymer which is itself

- 5 hydrophilic as it has been found that the exudate is less likely to coagulate rapidly. The use of such foams of hydrophilic polymer in dressings of the invention can allow the wound to be maintained in a moist condition even when the exudate produced has been absorbed and removed from the wound surface.

- 10 Favoured hydrophilic polymer foams are hydrophilic polyurethane and especially those which are made of crosslinked hydrophilic polyurethane.

- 15 In a further aspect the invention provides a low adherency wound dressing which consists essentially of a wound facing layer and an absorbent layer characterised in that the wound facing layer comprises a conformable apertured film and the absorbent layer comprises a conformable hydrophilic polyurethane foam.

- 20 Preferred foams can be made by reacting a hydrophilic isocyanate terminated polyether prepolymer with water. Favoured hydrophilic polyurethane foams of this type include those known as Hypol foams. Hypol foams can be made from Hypol hydrophilic prepolymers marketed by W.R. Grace and Co.

- 25 Suitable hydrophilic foam absorbent layers have a thickness of 0.5mm to 20mm, more suitably 0.8mm to 15mm and preferably 30 1mm to 12mm.

- The wound dressing of this invention may be in any convenient form. A preferred form is a pad of rectangular shape. Suitable sizes of such a pad are from 10cm to 20cm x 30cm. 40 Another preferred form is an elongate strip which may be in the form of a roll. Such a strip may be used as a bandage or may be used to prepare smaller dressings.

- 45 It is desirable that the wound dressings of this invention are sterile. The wound dressing of the invention is advantageously provided in bacteria impervious pouches. Such packed forms can be prepared under aseptic conditions or alternatively sterilised after packing by a conventional procedure. A favoured sterilisation procedure is heat sterilisation, for example by steam. Another favoured procedure is ethylene oxide sterilisation or gamma irradiation.

- 50 In another aspect the invention provides a process of making a low adherency wound dressing which comprises bringing together a comfortable apertured film layer, and an absorbent layer comprising a conformable hydrophilic polymer foam.

- 55 Normally the bringing together of the layers will be a lamination process.

- 60 The previously formed individual layers can be formed into a laminate by bonding the layers together in one or more laminating

processes. Suitable bonding methods include heat sealing or adhesive bonding providing the adhesive layer is moisture vapour transmitting.

- 70 In a preferred process the foam layer is formed in contact with the apertured film layer. This process is favoured as it reduces or eliminates the number of special bonding operations.

- 75 In a continuous process the wound dressing can be made in the form of a continuous strip which is then cut up into suitable sized dressings.

- The conformable hydrophilic polyurethane 80 foam can be made by mixing together an isocyanate terminated polyether having functionality of more than two with a surfactant and water and casting the mixture onto a surface. This surface advantageously may be the wound facing layer of the dressing.

- 85 Preferred isocyanate terminated polyethers include Hypols FHP 2000, 3000, 3001, 3002 and 2000HD marketed by W.R. Grace and Co. Hypols are described in a booklet published by W.R. Grace and Co. "Hypol: foamable hydrophilic polymers—laboratory procedures and foam formulation". Their preparation and use are disclosed in British Patent Specifications Nos. 1429711 and 1507232.

- 95 Suitable surfactants for forming conformable hydrophilic polymer foams include non-ionic surfactants. Favoured non-ionic surfactants are oxypropylene-oxyethylene block copolymers known as Pluronic marketed by 100 BASF Wyandotte. Preferred Pluronic include L64, F87, P38, P75 and L62. Another favoured non-ionic surfactant is a polyoxyethylene stearyl ether known as Brij 72 marketed by Honywell Atlas.

- 105 To prepare a suitable foam 100 parts by weight of Hypol FHP 2000, 2001, 3000, 3001, 2002 or 2000HD is mixed with 0.3 to 7 parts by weight of surfactant or mixtures of surfactants and 30 to 300 parts by weight of 110 water and the foaming mixture cast onto a surface. Typical foaming mixtures have a cream time of about 20 secs., a rise time of about 250 secs. and a cure time of about 400 secs.

- 115 In a continuous process for forming the foam the ingredients are fed into a continuous mixing and dispensing machine. Suitable conformable hydrophilic polymer foam layers can be made by casting the foaming mixture before it sets onto a suitable surface by means of a casting head.

- A suitable mixing and dispensing machine is known as Vario-Mix supplied by Prodef Engineering Limited. The foam mix can conveniently be delivered to the casting head by means of a "fishtail" die.

- 120 In a preferred process of forming the dressing the foam layer is produced in contact with the apertured layer.

- 130 Figure 1 illustrates a process of making the

conformable integral polymer nets of the wound dressing of the invention.

Figure 2 is a plan view of an embossed pattern sheet casting surface for forming an integral polymer net.

Figure 3 is a cross section through line A-A of Fig. 2.

In Fig. 1 a thermoplastic film (1) with an embossed pattern on its upper surface may be fed from roll (2) to the coating head (3) where a solution (4) may be cast into the recesses of the embossed sheet. The wet cast net (5) on the embossed sheet may be passed into an oven (6) where it is dried. The dried cast net (7) may then be separated from the embossed sheet (1) and wound up onto roller (8) where it may also be interleaved with a release paper (9) fed from the roll (10).

In an alternative and preferred process the dried cast net is left on the embossed sheet.

The coating head (not shown) has an adjustable doctor blade supported on a flat bed to meter the casting solution and side guides to regulate the width of the cast net. It is preferred that the doctor blade has a base portion which is thick enough to span the discrete raised areas of the embossed film to prevent the doctor blade catching in the recessed areas of the film. The doctor blade and the guides can be coated or made of a fluorocarbon polymer for example polytetrafluoroethylene to reduce friction against the film. Alternative casting heads using fixed or rotating rollers can also be used. A favoured coating head comprises an adjustable doctor blade which is supported on a soft base, for example a base consisting of a movable rubber belt around two rotatable rollers, to meter the casting solution.

Fig. 2 shows discrete raised areas (11) arranged in a square grid pattern to give a square grid pattern of recesses (12) on the embossed casting sheet.

In Fig. 3 a section through line A-A of Fig. 2 shows the discrete raised areas (11) in the shape of truncated square pyramids and recesses (12).

The integral nets of polyurethane can be made by casting the polyurethane in a flowable state onto a surface having a pattern of discrete raised areas and interconnected recessed areas and treating the cast net to form a solid integral net. The flowable state of the polyurethane can include solutions, dispersions, hot melts and powders which can be dried, coated, fused or otherwise to form a solid net. The casting surface may be in the form of a roll, an endless flexible belt or a length of sheet material. It is preferred that the casting surface has release properties to enable the formed net to be removed from the casting surface. The pattern of the discrete raised areas and interconnected recessed areas on the casting surface selected dictates the structure of the resulting net.

A preferred method of making the integral nets of polyurethane is by casting a solution of a thermoplastic polyurethane onto a melt embossed polyolefin sheet and drying the cast net in a hot oven.

Suitable casting solutions can contain 15% to 35% by weight of thermoplastic polyurethane, preferably 20% to 30% by weight. Favoured casting solutions contain 20 to 25% by weight of Estane 5702 or Estane 5703 in acetone. Another favoured solution contains 25% to 30% by weight of Estane 5714F in tetrahydrofuran or mixtures of tetrahydrofuran and acetone.

Analogous procedures may be used to prepare nets from other elastomers.

The melt embossed polyolefin sheet can be made by the method given in British Patent Specification No. 1055963. A suitable embossed polyolefin sheet has a pattern of 8 per cm raised areas in the form of square truncated pyramids 1mm wide and 0.5mm high with sides sloping to a 60° conical angle and longitudinal and transverse square grid recesses 0.25mm wide at the base and 0.75mm at the top. A favoured embossed polyolefin sheet has a pattern of 6 per cm raised areas in diagonal rows (45°) of square truncated pyramids 1.35mm wide at their base, 0.7mm wide at their top and 0.45mm high with sides sloping to a 70° conical angle.

A preferred embossed polyolefin sheet has a pattern of 4 per cm raised areas in diagonal rows (45°) of square truncated pyramids 2mm wide at their base, 1.425mm wide at their top and 0.5mm high with sides sloping to a 60° conical angle.

The solution of thermoplastic polyurethane can be cast onto the embossed polyolefin surface by means of a casting head consisting of a knife over a flat bed, knife over a roller or knife over a soft bed.

The wound dressing of the invention can contain a topically effective medicament. Most suitably the medicament is an antibacterial agent. Preferably the antibacterial agent is a broad spectrum antibacterial agent such as a silver salt such as silver sulphadiazine, and acceptable iodine source such as povidone iodine (also called polyvinyl pyrrolidone iodine or PVP/I), chlorhexidine salts such as the gluconate, acetate, hydrochloride or the like salts or quaternary antibacterial agents such as benzalkonium chloride or the like.

A preferred medicament for inclusion in the dressings of this invention is silver sulphuradiazine. A further preferred medicament for inclusion in the dressing of this invention is chlorhexidine which will normally be present as one of its aforementioned salts.

The medicament may be present by 0.2% to 20%, more usually from 0.3 to 10% and preferably 0.5 to 5% by weight of the dressing, for example 1%, 1.2% or 3% and the like. The medicament is present in the inven-

tion in the foam layer.

It is one of the surprising features of this invention that antibacterial agents can be incorporated into a hydrophilic polyurethane foam and will thereafter be available to aid in maintaining the wound to which the dressing is applied free of infection.

It is particularly surprising that medicaments such as silver sulphadiazine and chlorhexidine hydrochloride and the like can be incorporated into the proto foam prior to polymerisation since the presence of compounds containing basic nitrogen atoms may well have been expected to radically change the nature of the foam which has now been found not to occur.

The medicament may be introduced into the foam either by incorporation prior to foaming or by incorporation into the intact foam which has previously been prepared.

If the medicament is to be introduced prior to foaming then the medicament must either be free of reactive moieties which would react with the components of the mixture to be foamed (for example it must not contain free amino groups which could react with the isocyanates present) or else the medicament must be of low solubility so that its potential reactivity is suppressed. Thus for example medicaments such as silver sulphadiazine and chlorhexidine hydrochloride are easily incorporated into the foam by dispersing the desired amount of the medicament into the prepolymer mixture, for example dispersing it within the aqueous solution of the surfactant before mixing with the isocyanate containing materials. Most suitably the insoluble medicaments are in finely divided form and are most preferably micronised.

It has been found that more soluble salts such as chlorhexidine gluconate cannot be incorporated in this fashion since reaction with prepolymer components can occur and a more rigid and antibacterially ineffective foam results. Fortunately it has now been discovered that soluble medicaments can be included into the foam after it has been prepared by soaking the foam in a solution of the medicament. Thus for example a 2cm X 2cm dressing of this invention suspended in 50mls of 5% w/v solution of chlorhexidine gluconate for 48 hours and dried was found to possess antibacterial properties.

After fabrication the wound dressing of this invention can be washed with water to remove excess surfactant and then dried.

Surprisingly the method of drying has been found to affect the appearance of the dressing.

Dressing autoclaved using vacuum drying cycle have been found to tend to remain flat. The net layer has a puckered surface. Partially dried dressings, that is dressings containing low levels of residual water absorbed into the foam polymer but not into foam air spaces

have been discovered to be flat. This unanticipated effect is rendered even more useful since the dressing will remain flat if protected against loss of water, for example if packaged in a water proof pouch such as an aluminium foil pouch. In such partially dried dressings the net is not puckered.

Dressings containing residual amounts of water in this way have been found to have a pleasant cooling feel.

As previously indicated hereinbefore the dressings of this invention may be adapted to release an antibacterially effective amount of antibacterial agent into the wound covered by the dressing. Thus in an alternative aspect this invention provides a method of treating a wound so as to aid in rendering or maintaining it free of infection which comprises contacting the wound with a dressing of this invention adapted to release an antibacterial agent. Most aptly this aspect of the invention is employed in rendering or maintaining burns free of infection. The antibacterial agent present is favourably a silver salt such as silver sulphadiazine or a chlorhexidine salt such as chlorhexidine hydrochloride or a mixture thereof. Preferably the antibacterial agent present is silver sulphadiazine.

The absence of fibres in the dressing enhances the non-adherent properties of the wound dressings of the invention.

Preparation of Integral Polyurethane Net

A solution containing 30% by weight of Estane 5714F1 in tetrahydrofuran was cast into the recesses of a 15cm wide melt embossed high density polyethylene sheet by means of the blade over flat bed spreading technique. The sheet had a melt embossed pattern of 8 per cm raised areas in the form of square truncated pyramids 1mm wide at their base and 0.5mm high with sides sloping to a solid conical angle of 60°. The wet cast net on the embossed film was dried by passage through a hot air circulating oven at a temperature of 90°C to 100°C for two minutes. The dried cast net was separated from the embossed film and wound onto a roller interleaved with a double sided silicone release paper.

The resultant cast integral net of elastomeric polyurethane had the following properties: Weight 40gsm; thickness 100-125 microns; aperture size 0.3 to 0.4mm; tensile strength (g/2.5cm wide), machine direction 800 ± 51, transverse direction 664 ± 57; elongation at break %, machine direction 389 ± 24, transverse direction 374 ± 24.

Preparation of Integral Polyurethane Diamond Pattern Net (6 apertures/cm)

The net was cast in the same manner as the preceding square net except that the casting sheet had a melt embossed pattern of 6 per cm raised areas in diagonal rows (45°) of

square truncated pyramid 1.35mm wide at the base and 0.45mm high with sides sloping to a conical angle of 70°.

5 Example 1

Preparation of a low adherency wound dressing

Wound dressings consisting of hydrophilic polyurethane film absorbent layer bonded to an integral net of polyurethane were prepared by forming the foam layer on the polyurethane integral net.

A mixture of Brij 72 (22.5g of 2% aqueous emulsion) and Pluronic F87 (0.5ml of a 10% aqueous solution) was added to Hypol FHP 3001 (15g) in a beaker and thoroughly mixed by stirring with a metal spatula until the Hypol was uniformly dispersed (20 seconds). The foaming mixture was poured into a 15cm wide brass hand spreader box set at a gap of 1.8mm above the cast integral polyurethane net of the Description. The spreader box was then drawn by hand along the net surface to leave a foam layer on the net. The foam layer was free of large craters and was well bonded to the net.

Alternatively the wound dressing can be made in a similar manner by coating the foam into the integral polyurethane net on the embossed film carrier.

Sample wound dressings of Example 1 and a comparison hydrophilic polyurethane foam were washed with distilled water and dried at 40°C for 12 hours before being tested for wound adherency.

Example 2

Brij 72 (30g as a 2.5% aqueous solution) was added to Hypol FHP 3001 (20g) in a beaker and mixed by stirring with a metal spatula and then with a mechanical stirrer until the Hypol was uniformly dispersed (approximately 20 seconds). The foaming mixture was cast onto a 6 aperture per cm diamond pattern net as described above on its embossed film carrier by means of a blade over flat bed coating head set at a gap of 0.1mm. After 15 minutes the embossed film was removed from the net surface of the strip and the strip cut into 30cm X 15cm wound dressings. The dressings were washed in two changes of 1 litre of distilled water and dried in air.

55 Example 3

Wound dressings were prepared in the same manner as Example 2 using a gap setting of 0.5mm instead of 0.1mm.

60 Example 4

Wound dressings were prepared in the same manner as Example 2 using a gap setting of 1.0mm instead of 0.1mm.

65 Example 5

The dressings of Example 4 were washed but only partially dried by padding with an absorbent towel.

The following Examples 6 to 10 illustrate the preparation of medicated wound dressings of the invention.

Example 6

Wound dressings were prepared in the same manner as Example 3 except that silver sulphadiazine powder (0.2g) was blended into the Brij 72 emulsion with a high speed shear mixer prior to the addition of Hypol FHP 3001.

80

Example 7

Wound dressings were prepared in the same manner as Example 6 using 1g of chlorhexidine hydrochloride powder instead of silver sulphadiazine powder (0.2g).

85

Example 8

Wound dressings prepared as in Example 3 were soaked for 10 minutes in a tray containing an aqueous solution of chlorhexidine gluconate (5% weight/volume) and air dried.

90

Example 9

Wound dressings were prepared in the same manner as Example 8 using an aqueous solution of chlorhexidine acetate (5% weight/volume) instead of an aqueous solution of chlorhexidine gluconate.

95

100 Example 10

Wound dressings were prepared in the same manner as Example 8 using an aqueous solution of povidone iodine (10% weight/volume) instead of an aqueous solution of chlorhexidine gluconate.

105

Example 11

Wound dressings consisting of a hydrophilic polyurethane absorbent layer bonded to an integral net of polyurethane were prepared in the same manner as the wound dressings of Example 5 by forming the foam layer on the polyurethane integral net.

110

115 Example 12

Wound dressings were prepared in the same manner as Example 11 using 20g instead of 30g of Brij 72.

120 Example 13

Wound dressings were prepared in the same manner as Example 11 using 40g instead of 30g of Brij 72.

125 Example 14

Wound dressings were prepared in the same manner as Example 11 with 0.5ml of Pluronic L64 (10% aqueous solution) added to the surfactant emulsion.

Example 15

Wound dressings were prepared in the same manner as Example 14 using Pluronic F68 in place of Pluronic L64.

Example 16

Wound dressings were prepared in the same manner as Example 14 using Pluronic F108 instead of Pluronic L64.

Example 17

Wound dressings were prepared in the same manner as Example 1 using a cast polybutadiene (Ref. RB 830) net (8 apertures per cm) instead of a polyurethane net.

Example 18

Preparation of Integral Diamond Pattern Net (4 apertures per cm)

- 20 A solution containing 20% by weight of Estane 5714F in 60/40 (weight by weight) mixture of tetrahydrofuran/acetone was cast into the recesses of a 15cm wide melt embossed high density polyethylene sheet by means of a blade over soft bed coating technique. The sheet had a melt embossed pattern of 4 per cm raised areas in diagonal rows (45°) of square truncated pyramids 2mm wide at their base, 1.42mm wide at their top and 0.5mm high with sides sloping to a conical angle of 60°. The cast net on the embossed film was dried by passage through a hot air oven at a temperature of 80°C for two minutes.
- 30 The net had a weight per square metre of 33g and had 4 per cm apertures of approximately 1.4mm in size.

Example 19

- 40 Wound dressings were prepared in the same manner as Example 18 using a cast polybutadiene (Ref. RB 830) net (6 apertures per cm) instead of a polyurethane net.

Preparation of the Absorbent layer

- 45 Using a two component dispensing unit (Vario-mix supplied by Prodef Engineering Limited) a foaming mixture was formed by mixing Hypol FHP 2002 and Brij 72 (2% aqueous solution) in the ratio of 1:2.25. The foaming mixture was fed into the coating head by means of an output nozzle in the form of a 15cm 'fishtail die' and coated onto the cast polyurethane net (on embossed film) by means of a knife over roller coating head set at a gap of 1mm. The cast foam was dried by passage through an air circulating oven at a temperature of 50°C for 5 minutes. The embossed film was then removed from the foam-net composite strip and the strip cut into dressings of suitable size for adherence testing. The dressing had a thickness of 2.3mm and a weight per square metre of 340 grams.

Adherence Testing

When tested on guinea pigs the dressings of Examples 4, 24 and 26 required only half the energy to remove them did "Melolin" (a commercial non-adherent dressing) and Examples 1 and 2 required respectively about one eighth and one third the energy to remove them than did "Melolin".

CLAIMS

- 75 1. A low adherence wound dressing which consists essentially of a wound facing layer and an absorbent layer characterised in that the wound facing layer comprises a conformable apertured film and the absorbent layer comprises a conformable hydrophilic foam.
- 80 2. A low adherence wound dressing as claimed in claim 1 in which the hydrophilic foam is a foam of a hydrophilic polymer.
- 85 3. A low adherence wound dressing as claimed in claim 2 in which the hydrophilic polymer is hydrophilic polyurethane.
- 90 4. A low adherence wound dressing as claimed in any of claims 1 to 3 in which the hydrophilic foam comprises an open cell foam with a cell size of 50 microns to 500 microns.
- 95 5. A low adherence wound dressing as claimed in any of claims 1 to 4 in which the hydrophilic foam comprises an open cell foam in which 30% to 60% of the total membrane area of the cells are membrane openings.
- 100 6. A low adherence wound dressing as claimed in any of claims 1 to 5 in which the wound facing layer comprises a conformable integral net of an elastomer.
- 105 7. A low adherence wound dressing as claimed in any of claims 1 to 6 in which the conformable apertured film comprises a polyurethane.
- 110 8. A low adherence wound dressing as claimed in any of claims 1 to 7 in which the apertured film has 4 to 40 apertures per cm with a dimension of 0.5 to 2.5mm.
- 115 9. A low adherence wound dressing as claimed in any of claims 1 to 8 in which the dressing contains a topically effective medicinal agent.
10. A low adherence wound dressing as claimed in claim 9 in which the topically effective medicament comprises an antibacterial agent and is located in the hydrophilic foam layer.
11. A sterile low adherence wound dressing as defined in claims 1 to 10 within a bacteria impervious pack.

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